HFI-35 4/28/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

JEW 4/14/97

M822N

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-45

April 14, 1997

Nannette Polumbo, President
Medical Department Store
1203 South East 9th Terrace
Cape Coral, Florida 33990

Dear Ms. Polumbo:

Inspection of your medical gas filling operation located at 8595 College Parkway, Fort Myers, Florida, on March 19, 1997, by FDA investigator José R. Rodríguez, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical Oxygen USP causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to appropriately test each lot of compressed medical Oxygen USP for purity and identity prior to release for distribution. Testing is inadequate in that records documenting calibration and maintenance of the [redacted] Oxygen Analyzer used by your firm are not maintained. There is no assurance that the analyzer is being calibrated or maintained properly as specified by the manufacturer, or that personnel performing calibration and testing have been properly trained. Failure to properly calibrate and maintain your oxygen analyzer makes any determination of purity unreliable.

Established written procedures for calibration and maintenance of equipment, completion of batch records, oxygen testing, record keeping, and supervisory review are not being followed. Written procedures are not established for label reconciliation, product recall, or personnel training. Batch production records are incomplete, not maintained, and fail to document that each significant step in the manufacturing operation was accomplished. For example, batch records fail to

document all fill and post fill cylinder testing, such as pressure, temperature, and leak tests. There is no documentation that batch records are reviewed and approved by a supervisor prior to release.

Review of labeling used on some cylinders of compressed medical oxygen filled by your firm reveals the products to be misbranded within the meaning of Section 502(a) of the Act in that labels bear the unqualified name of another firm, B&F Medical Products, in addition to the name and place of business of your firm. Except as provided in 21 CFR 201.1(h)(1), no person other than the manufacturer, packer, or distributor may be identified on the label of a drug product. As the refiller, your firm is considered to be the manufacturer. Therefore, only your firm's name and place of business should appear on the label.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

for Douglas D. Tolen
Director, Florida District

cc: Debra Roberts, Manager
Medical Department Store
8595 College Parkway
Fort Myers, Florida 33919

bcc:
HFR-SE200/RF/EI JKT
HFR-SE240/JEW/LGL JKT/WL FILE
HFR-SE250/MAC/PRD
TGF/JRR
HFI-35 (PURGED)
HFA-224
HFC-210 (CFN #1058999)
HFD-300

TRAK 97-33

DFT:4/2/97:JRR
REV:4/11/97:JEW886

final: 4/14/97 mrj

JEW